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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,132

10/23/2006

Glen Ernst

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ASTRA ZENECA PHARMACEUTICALS LP  
GLOBAL INTELLECTUAL PROPERTY  
1800 CONCORD PIKE  
WILMINGTON, DE 19850-5437

EXAMINER

MURRAY, JEFFREY H

ART UNIT

PAPER NUMBER

1624

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/573,132	<b>Applicant(s)</b> ERNST ET AL.	
	<b>Examiner</b> Jeffrey H. Murray	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 15 is/are pending in the application.
- 4a) Of the above claim(s) 4-10, 12 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/23/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. This action is in response to a restriction election filed on October 31, 2007.

There are thirteen claims pending and four claims under consideration. The applicants have elected Group XVII with traverse. There are thirteen claims pending and four claims under consideration. Claims 4-10, 12 and 15 are withdrawn from consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 13 and 14 have been cancelled. This is the first action on the merits. This invention relates to diazabicyclononane compounds or pharmaceutically acceptable salts thereof, processes for preparing them, pharmaceutical compositions containing them and their use in therapy. The relation relates more particularly to such compounds which are nicotinic acetylcholine receptor agonists.

2. Applicants have properly pointed out that under the restriction requirement, a “five-membered ring heterocyclic ring with at least one nitrogen atom” *does* include such heterocyclic ring systems as thiazolyl, oxazolyl and imidazolyl and these ring systems will be considered in the examination where appropriate.

3. Applicant’s election of Group III in the reply filed on October 31, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore the restriction is proper and deemed **FINAL**.

***Priority***

4. Acknowledgment is made of Applicant's claim for domestic priority. This application, U.S. Application No. 10/573,132, filed March 23, 2006, is a national stage application of PCT application PCT/GB04/04130, filed September 24, 2004, and claims foreign priority to U.S. Provisional Application No. 60/506,664, filed September 24, 2003.

***Specification***

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

6. The specification does not provide adequate support for the terms in Claim 1. Claim 1 states in part, "...D is selected from hydrogen, halogen, C<sub>1</sub>-C<sub>6</sub> alkyl, phenyl, biphenyl, phenylsulphanyl or pyridyl, wherein D may have 1, 2 or 3 substituents selected from halogen, alkoxy or trifluoromethyl with the proviso that the compound is not 4-benzyl-1,4- diazabicyclo[3.2.2]nonane." The specification on page 2 and 3 specifically define D as, "D is selected from hydrogen, C<sub>1</sub>-C<sub>6</sub> alkyl, phenyl, phenylsulphanyl or pyridyl, wherein D may have 1, 2 or 3 substituents selected from halogen, alkoxy or trifluoromethyl..." The difference is the insertion into the claims after the restriction election of the terms, "halogen" and "biphenyl". The specification does give a single species example under each of these genus categories. However, the written description requirement cannot be satisfied by disclosing only one embodiment or species of invention while claiming whole genus or claiming different embodiment or

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species. *Tronzo vs. Biomet inc.*, 41 USPQ2d 1403 (S.D. Fla. 1996). Therefore a single example of a bromo or biphenyl compound in the specification cannot uphold an entire genus such as “halogen” or “biphenyl.” A claim for a specific compound, such as the 2 aforementioned examples, would be patentable as a specific compound claim or species claim, but not as a generic or genus claim. Appropriate correction is necessary.

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant’s cooperation is requested in correcting any of the errors of which applicant may become aware of in the specification.

#### ***Claim Objections***

8. Claim 1 is objected to because of the following informalities:

Claim 1 defines a proviso at the end of the claim. With the Group III election that was made by applicants, the compound cannot be “4-benzyl-1,4-diazabicyclo[3.2.2]-nonane because there needs to be a 5-membered heterocycle present. Examiner suggests removing any and all superfluous provisos in light of the restriction election. Appropriate correction is required.

9. Claims 4-10, 12 and 15 are objected to because of the following informalities:

Claims 4-10, 12 and 15 are all drawn to non-elected claims. These claims need to be withdrawn due to the restriction election of Group III. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup>***

10. Claims 1-3 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. See the above argument, under the "Specification" heading, paragraph 6. Appropriate correction is necessary.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 1-3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galli, et. al. U.S. Patent No. 6,844,337 (hereafter '337) in view of *In re Norris* (CCPA 1950) 179 F2d 970, 84 USPQ 458; *In re Finley* (CCPA 1949) 174 F2d 130 and 135, 81 USPQ 383 and 387. The current application recites diazabicyclononane compounds or pharmaceutically acceptable salts thereof, processes for preparing them, pharmaceutical compositions containing them and their use in therapy.

'337 teaches a group of compounds which are similar in scope to the current application. The current application teaches a compound of the structure Q-E-D where Q is represented by a diazacyclononane with a methylene group stemming from the 1-nitrogen. '337 also contains the same core structure as the present application. The difference lies in the representation of the E variable. The current application defines E as thiazolyl, oxazolyl or imidazolyl. '337 defines E as a "5-isoxazolyl" group. Therefore the difference between the current application and the prior art is the location of the oxygen and nitrogen atoms in the 5-membered ring system. Both the current application and '337 are being used for the same purpose, that of a nicotinic receptor agonists.

The court decisions of *In re Norris* (CCPA 1950) 179 F2d 970, 84 USPQ 458 and *In re Finley* (CCPA 1949) 174 F2d 130 and 135, 81 USPQ 383 and 387 discusses isomers. Compounds having the same radical at different positions on the nucleus are position isomers. Their properties are often so nearly alike as to present difficulties in identification or separation. *Ex parte Mowry* (POBA 1950) 91 USPQ 219. Position isomerism involves close structural similarity which must be considered along with all other relevant facts in determining the issue of obviousness under 35 USC §103. *In re Wiechert* (CCPA 1967) 370 F2d 927, 152 USPQ 247. The cases state, "a novel useful compound which is isomeric with a compound of the prior art is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compound." *In re Norris* (CCPA 1950) 179 F2d 970, 84 USPQ 458; *In re Finley* (CCPA 1949) 174 F2d 130 and 135, 81 USPQ 383 and 387.

Relating the information from *In re Norris* to '337, it would have been obvious for a person of ordinary skill in the art to try replacing the "5-isoxazolyl" group with an oxalyl group as the "E" substituent in the current application. Due to the numerous chemical property similarities of an isoxazole and an oxazole, this substitution would be attempted by anyone skilled in the art.

Claims 1-3 and 11 are obvious because the substitution of one known element (oxazolyl) for another (isoxazolyl) would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

### ***Conclusion***

9. Claims 1-3 and 11 are rejected.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is (571) 272-9023. The examiner can normally be reached on Mon-Thurs. 7:30-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a US PTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey H Murray/  
Examiner, Art Unit 1624

/James O. Wilson /  
Supervisory Patent Examiner  
Art Unit 1624